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RESPONSE UNDER 37 C.F.R. §1.116
EXPEDITED PROSECUTION
ART UNIT 3762

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: M. Rigdon Lentz

Serial No.: 09/083,307

Art Unit: 3762

Filed: May 22, 1998

Examiner: W. Noggle

For: *METHOD FOR COMPOSITIONS FOR TREATMENT OF CANCERS*

Assistant Commissioner for Patents
Washington, D.C. 20231

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RESPONSE

Sir:

The following remarks are in response to the Office Action mailed January 4, 2000.

Rejections under 35 U.S.C. §103(a)

Claims 1-4, 8, 9, 16, 18-20, and 22 were rejected under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 4,708,713 to Lentz. Claim 7 was rejected under §103 as obvious over Lentz in combination with Chen, et al. J. Neuropathology and Experimental Neurology.56(5), 541-550 (1997). Claims 5, 6, 10-15, 17 and 23 were rejected under §103 as obvious over Lentz in combination with U.S. Patent No. 5,861,483 to Wolpe.

Lentz

As the examiner correctly notes, Lentz discloses essentially the same procedure as claimed by applicant, but with one major difference: Lentz discloses removal of all blood components of 200,000 mw or less. As a result, the patient loses all of their IgG and IgA antibodies, which are extremely important to fight infection. As the examiner is also aware,

infection is a major problem for cancer patients, so the first method would not have been developed if the patentee had even remotely believed that one did not have to remove the immunoglobulins. However, it simply had not been determined even as of the issue date of the '713 patent (1987), what the active component was that was being removed by the procedure, which allowed the patient to then fight off the cancer. It has taken years of subsequent work to determine that the "bad" component which is removed by the procedure is a relatively low molecular weight component, allowing the substitution of a filter with a lower molecular weight cutoff.

There is absolutely no teaching in the '713 patent that would lead one of skill in the art to believe that a lower molecular weight cutoff could be used. It has been well established by the Courts that the reference(s) cited under §103 must not only disclose the elements applicant is claiming but the motivation to use them as applicant has done, with an expectation of success. That test cannot be met by the '713 patent. In contrast the statements on page 4 that Lentz does not teach the criticality of the filter size, at col. 6, lines 34-46, Lentz specifically states that the **immunosuppressive element** "is believed to be an IgG type immunoglobulin molecule. The other fraction has a molecular weight between about 200,000 and 1,000,000 and is believed to be an immune complex." col. 6, lines 43-46. Accordingly, not only is there no disclosure of the claimed elements in Lentz, there are two specific statements **arguing the criticality of the higher molecular weight cutoff of the filter**, teaching away from what applicant has now developed. One skilled in the art would simply not practice the currently claimed method because Lentz teaches that it would **not** be successful!

With regard to claim 9, the claim is to a device which removes an **immunosuppressive** component, which has a molecular weight cutoff of less than immunoglobulins (i.e., IgG), which

is used in conjunction with a vaccine that elicits an immune response. This immunosuppressive component prevents the body from attacking the cancers; it does not elicit a reaction against the body. The same comments apply to claim 16: while radiation is known to be effective in treating cancer, it does it by killing the cells, not by stimulating an immune response. In contrast, it is well established that radiation *decreases* a cancer patient's ability to fight the disease.

Chen

Chen teaches that soluble TNF-alpha receptors suppress the patients ability to fight cancers. As discussed above, Lentz teaches that something about the size of an immunoglobulin, or larger, is instrumental in suppressing a patient's ability to fight a tumor. Soluble TNF-alpha receptors are 55,000 and 75,000 daltons in size (page 541, col. 1). The combination of Lentz with Chen is **not** the same as what applicant is claiming. Moreover, there is nothing that would lead one to believe that you could remove only the smaller molecular weight molecules and still effectively treat the cancer based on reading Lentz. Therefore, one skilled in the art would be led **away** from the combination of Lentz and Chen, **not to a modified combination**.

Wolpe

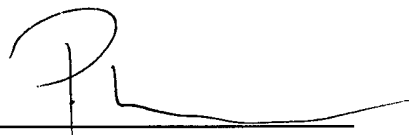
Wolpe still does not make up for the deficiency of Lentz. Lentz clearly states that there is an immunosuppressive element of a molecular weight similar to that of an immunoglobulin or immunoglobulin complex which must be removed for a patient to effectively fight the cancer. Wolpe states that certain factors are known which enhance the immune system. Wolpe does not address the issue of whether or not there is an immunosuppressive component having a molecular weight in the critical range between that which is now claimed and that which is taught in the thirteen year old patent to Lentz, prior to many subsequent studies which were

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required to determine that the immunosuppressive element does **not have a molecular weight similar to that of an immunoglobulin or immunoglobulin complex**. The difference is important: by using the lower molecular weight cutoff, the patient can keep their own immunoglobulin, helping them to more successfully fight off infection.

In summary, no where has the examiner provided any motivation as to why one of ordinary skill in the art would be led to change the filter device of Lentz to **exclude** the very molecules he says must be removed for the treatment to be effective. Accordingly, it is believed that all of claims 1-23 are novel and non-obvious over the cited art. All claims 1-23 as currently pending are attached in an appendix to facilitate the examiner's review.

Respectfully submitted,



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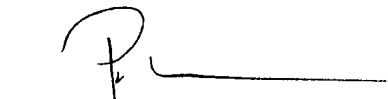
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I hereby certify that this Amendment, along with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on the date shown below with

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Date: April 4, 2000



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